

CLAIMS

1. A disposable test strip for use in a test meter of the type which receives a disposable test strip and a sample of blood and performs an electrochemical analysis of the amount of a blood analyte in the sample, comprising:

(a) a substrate;

(b) a first conductive element disposed on the substrate;

(c) a second conductive element disposed on the substrate in sufficient proximity to the first conductive element to allow the completion of an electrical circuit between the first and second conductive elements when a sample of blood is placed on the test strip;

(d) a non-conductive integrated reagent/blood separation layer disposed over the first conductive element, said integrated reagent/blood separation layer comprising reagents for the electrochemical detection of the analyte dispersed in a non-conductive matrix effective to exclude blood cells from the surface of the first conductive element while permitting access to the first conductive species by soluble electroactive species;

(e) contacts for making an electrical connection between the first and second conductive elements and the test meter; and

(f) an insulation layer disposed over at least the first conductive elements, said insulation layer having a first aperture therein aligned with the first conductive element, wherein the non-conductive integrated reagent/blood separation layer contacts the first conductive element through the aperture in the insulation layer and wherein the non-conductive integrated reagent/blood separation layer is formed covering the entire first aperture, thereby leaving no portion of the first conductive element directly exposed to a sample applied to the test strip.

2. The test strip of claim 1, wherein the integrated reagent/blood separation layer comprises an enzyme for oxidation of glucose and a redox mediator effective to transfer electrons from the enzyme to the first conductive element.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/00620

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : G01N 27/26

US CL : 204/403

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 204/403, 415; 205/777.5, 778; 427/2.11, 2.12, 2.13

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

CAPLUS

search terms: sensor, detector, test strip, oxidase, glucose, blood, silica?, cab-o-sil

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 0207370 A2 (JONES) 07 January 1987, the abstract; claims 2, 5, and 8; and page 6, line 5 - page 7, line 29.	1-23
Y	US 5,185,256 A (NANKAI et al.) 09 February 1993, the abstract and Figures 3 and 8.	1-23
Y	US 5,601,694 A (MALEY et al) 11 February 1997, the abstract; Figures 9A and 9B; col. 17, ll. 46-63; col. 19, ln. 34-45; col. 22, ll. 43-48; and col. 17, ln. 46 - col. 18, ln. 46.	1-23

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*G* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

30 MARCH 2000

Date of mailing of the international search report

25 APR 2000

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

ALEX NOGUEROLA

Telephone No. (703) 308-0661

DEBORAH THOMAS
PARALEGAL SPECIALIST

FOR THE PURPOSES OF INFORMATION ONLY

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PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents
United States Patent and Trademark
Office
Box PCT
Washington, D.C. 20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 04 October 2000 (04.10.00)	
International application No. PCT/US00/00620	Applicant's or agent's file reference
International filing date (day/month/year) 11 January 2000 (11.01.00)	Priority date (day/month/year) 12 January 1999 (12.01.99)
Applicant MCALEER, Jerome, F. et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
30 June 2000 (30.06.00)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

<p>The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No.: (41-22) 740 14.35</p>	<p>Authorized officer C. Cupello</p> <p>Telephone No.: (41-22) 338.83.38</p>
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PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: MARINA LARSON
OPPEDAHL & LARSON LLP
P.O. BOX 5068
DILLON CO 80435-5068

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing
(day/month/year)

21 MAY 2001

Applicant's or agent's file reference

SELF.P-016WO

IMPORTANT NOTIFICATION

International application No.

PCT/US00/00620

International filing date (day/month/year)

11 JANUARY 2000

Priority Date (day/month/year)

01 DECEMBER 1999

Applicant

SELF CARE, INC.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301)

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

REPORTING LETTER _____

COMPUTER DOCKET _____

PAPER DOCKET _____

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7/12/01

MAY 24 2001

PS

Name and mailing address of the IPEA/US

Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

ALEX NOGUEROLA

DEBORAH THOMAS
PARALEGAL SPECIALIST

Telephone No. (703) 308-0661

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 25 MAY 2001

WIPO

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Applicant's or agent's file reference SELF.P-016WO	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US00/00620	International filing date (day/month/year) 11 JANUARY 2000	Priority date (day/month/year) 01 DECEMBER 1999
International Patent Classification (IPC) or national classification and IPC IPC(7): G01N 27/26 and US Cl.: 204/403		
Applicant [SELF CARE] INC Inverness Medical Technology, Inc.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 1 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 30 JUNE 2000	Date of completion of this report 22 APRIL 2001
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer ALEX NOGUEROLA DEBORAH THOMAS PARALEGAL SPECIALIST
Facsimile No. (703) 305-3230	Telephone No. (703) 308-0661

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/00620

I. Basis of the report

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed
- ☒ the description:
pages (See Attached) _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☒ the claims:
pages (See Attached) _____, as originally filed
pages _____, as amended (together with any statement) under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☒ the drawings:
pages (See Attached) _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☒ the sequence listing part of the description:
pages (See Attached) _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE
- ☒ the claims, Nos. NONE
- ☒ the drawings, sheets/~~fig~~ NONE

5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

**Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/00620

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. statement**

Novelty (N)

Claims 1-23 YESClaims NONE NO

Inventive Step (IS)

Claims 1-23 YESClaims NONE NO

Industrial Applicability (IA)

Claims 1-23 YESClaims NONE NO**2. citations and explanations (Rule 70.7)**

Claims 1-23 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a non-conductive integrated reagent/blood separation layer disposed in disposable test strip or method of making a disposable test strip as provided by of each of claims 1 and 11, respectively.

The invention has utility for producing a sensor for monitoring glucose in a diabetic individual.

----- NEW CITATIONS -----
NONE

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/00620

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 11 is objected to under PCT Rule 66 2(a)(v) as lacking clarity under PCT Article 6 because the claim is indefinite for the following reason(s): there is no antecedent basis for "said integrated reagent/blood separation layer" in line 10.

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

I. BASIS OF REPORT:

This report has been drawn on the basis of the description,
page(s) 1-17, as originally filed.
page(s) NONE, filed with the demand.
and additional amendments:
NONE

This report has been drawn on the basis of the claims,
page(s) 19-21, as originally filed.
page(s) NONE, as amended under Article 19.
page(s) NONE, filed with the demand.
and additional amendments:
Page 18, file with the letter of October 04, 2000.

This report has been drawn on the basis of the drawings,
page(s) 1-9, as originally filed.
page(s) NONE, filed with the demand.
and additional amendments:
NONE

This report has been drawn on the basis of the sequence listing part of the description:
page(s) NONE, as originally filed.
pages(s) NONE, filed with the demand.
and additional amendments:
NONE